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THE DEVELOPMENT AND APPLICATION OF A TENDON PROSTHESIS FOR THE --ETC(U)
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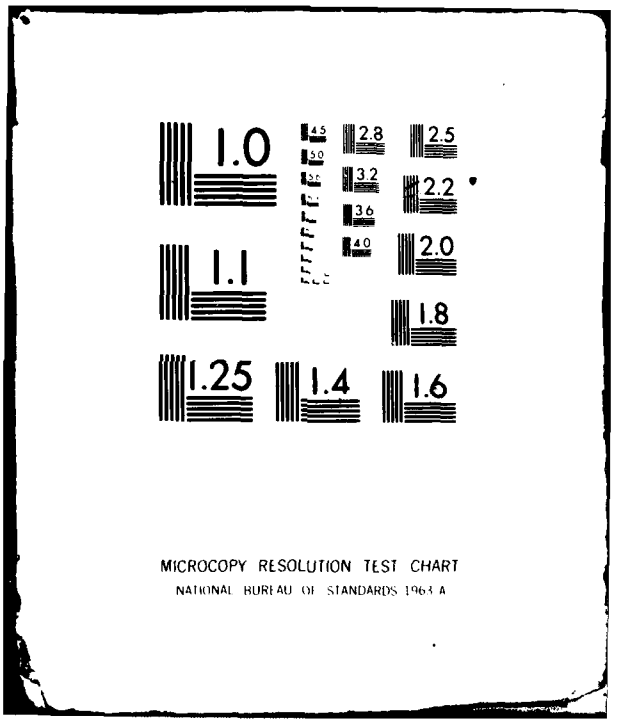
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THE DEVELOPMENT AND APPLICATION OF A TENDON PROSTHESIS FOR THE EARLY FUNCTIONAL RESTORATION OF THE HAND

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by

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Scott H. Jaeger, M.D.
John J. Konikoff, Ph. D., P.E.

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20. ABSTRACT *(Continue on reverse side if necessary and identify by block number)*

The primary goal of this program was the development of an active tendon prosthesis. Several aspects of this investigation resulted in a prototype design of an active artificial tendon that appears to meet this goal.

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20. ABSTRACT (cont)

The final design of the active artificial tendon encompasses a polyester shaft having a looped proximal end and a sintered titanium plug permanently attached to the distal end for attachment to bone. The entire device, with the exception of the 3mm. long sintered plug, is coated with silicone rubber to enhance its gliding ability which is a prerequisite criterion needed to reduce the probability for the production of adhesions following implantation surgery.

Short term implant studies in both primates and humans have shown promise.

SUMMARY

The primary goal of this program was the development of an active hand tendon prosthesis. During the past 6 months (December 78 thru 31 May 1979) the several aspects of this investigation resulted in a prototype design of an active artificial tendon (AAT) that appears to meet this goal.

The final design of the AAT encompasses a polyester shaft having a looped proximal end and a sintered titanium plug permanently attached to the distal end for attachment to bone. The entire device, with the exception of the 3mm. long sintered plug, is coated with silastic (silicone rubber) to enhance its gliding ability which is a requisite criterion needed to reduce the probability for the promotion of adhesions following implantation surgery. In addition, the silastic coating is essentially benign within the milieu of the anatomic locus of the hand/finger thus eliminating any potential interaction.

Long term implant experience is not as yet available due to the non-renewal of the study contract. However, short-term implant studies in both primates and humans have shown promise.

1. Design Studies

A. Distal Attachment

As previously indicated, the method of choice, derived during the 1977-78 study period evolved around the application of a sintered titanium plug permanently attached to the distal end of the ACT shaft. By drilling into the distal phalanx and locating the sintered plug within the cortex, the natural regenerative system commenced the infiltration of new bone into the interstices of the sintered plug so that, in time, a solid attachment resulted.

The plug shown in fig. 1 , is 4 mm. dia. by 8 mm. long with a center hole of 115 mm. diameter. The dacron tape is held in position within 1.5 mm. inside diameter by the addition of a cross-pin fixation system that prevents the tape from being pulled through the plug. By this method, the need for acrylic bone or tissue cement is not necessary.

Pull testing done on sample looped dacron shafts results in failure at values of 130, 135, 156, 172 and 195 lbs. for 5 different samples. Average stretch of the dacron cord at failure was 5%. These values are in the same range as those values derived from shearing trabeculae in a baboon model which showed a shear stress of about 100 p.s.i. (25 Dg./ gm^2). Since the surface area of the porous sleeve is 1.07 cm^2, the pullout force for the implant is about 165 lbs. which is within the mean range of the pull testing data reported above (158 lb $\pm$28).

In order that the abrasive wear on the cord is minimized where the cord end titanium plug interface, the inside bone and the proximal end of the porous metal sleeve is coated and penetrated with ultra high molecular weight polyethylene.

An alternate distal attachment has been more fully evaluated during this latter period. The approach utilized a prefabricated high carbon steel plate with bone fixation points that is attached to the distal end of the Hunter Housner Tendon Implant (HHTI). In practive, the HHTI is properly positioned automatically so that the metal fixation plate is located on top of the phalanx and is then affixed to the bone using a screw similiar material. This system has been tested in primates and humans and has demonstrated its effectiveness as a means for short term (4 - 8 wks.) attachment of a gliding artificial tendon. A new technique for attaching the distal metallic end plate to the dacron take has been evolved. It consists of the application of a heat to the dacron area to the time when it is molded into the distal end slot. Times ranging from 20 to 30 seconds had little effect on the pull-out (separation) load. The mean pull-out loading was 24.8 lbs. and has been demonstrated in trials in primates and humans to be sufficient for the proper application of a sliding active artificial tendon implant. Figure 2 illustrates the HHTI incorporating the metal end fixation plate. Figure 2-A is the active tendon package for limited clinical trial.

B. Proximal End Attachment

As indicated in the annual report of November 1978, the soft loop design is our choice for the proximal end attachment. Although several candidate methods are available for selection as the optimum approach to incorporate the looped end onto the main body of the shaft, the shortened study period did not permit a selection to be made. To date, the method being used requires sewing the end into the shaft (Figure 2) as opposed to the approach where in the fibers are woven or braided into the shaft (Figure 1) much as wire rope is wound aboard naval vessels.

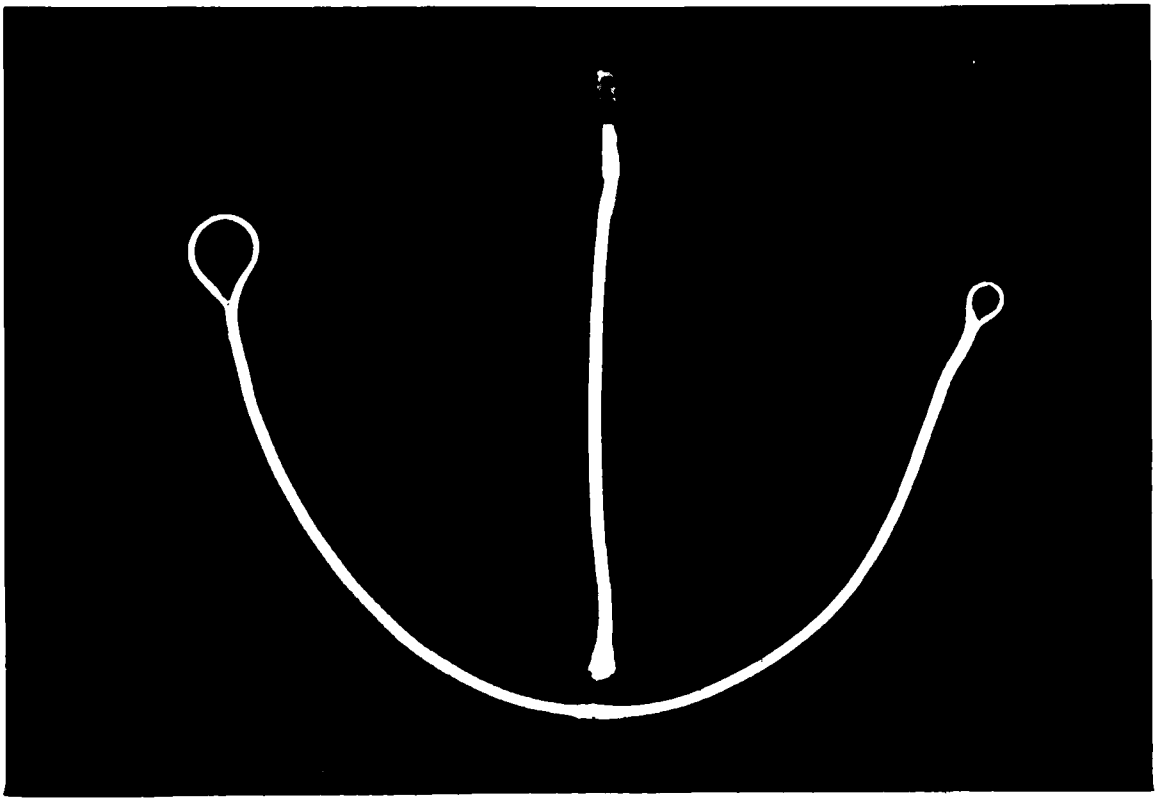

FIGURE I

The major difficulty encountered by this method is the increase in diameter of the shaft thus increasing the possibility of the artificial tendon sticking or otherwise not gliding preferably through the pulleys or sheaths.

The thermal joining process (a technique wherein the looped end and shaft are welded together) has been proven to require an extensive test program in order that optimum heat application can be used for joining while, at the same time, structural integrity of the basic material is not sacrificed.

C. Shaft Design

The braided open tube has been tested preliminarily and results indicate that it has desirable properties (Figure 1). The pull testing conducted on the sintered plug systems used the braided open tube design. The anticipated problem of excessive elongation was resolved by varying the warp/woof ratios, so that an average elongation at fresh point (158 lbs.) of 5% resulted (See par. 1A above).

11. Basic Studies

A. Pulley Study

A study was conducted to biomechanically determine the necessary pulleys to be preserved in tendon exploration, and the optimal sites for pulley reconstruction to maximize results. The normal anatomic pulley system is a continuum of reinforcing fibres made up of 5 annular and 3 cruciate pulleys, with one variable fibre area between A_1 and A_2, as well as superficialis reinforcement of the profundus tendon at the chiasm of Camper. Using 25 fresh human cadaver hands, fingers were dissected leaving tendon and joint systems intact. The metacarpals were bolted to a board permitting goniometric measurement and photographic study of the joints as the profundus tendon was pulled through a

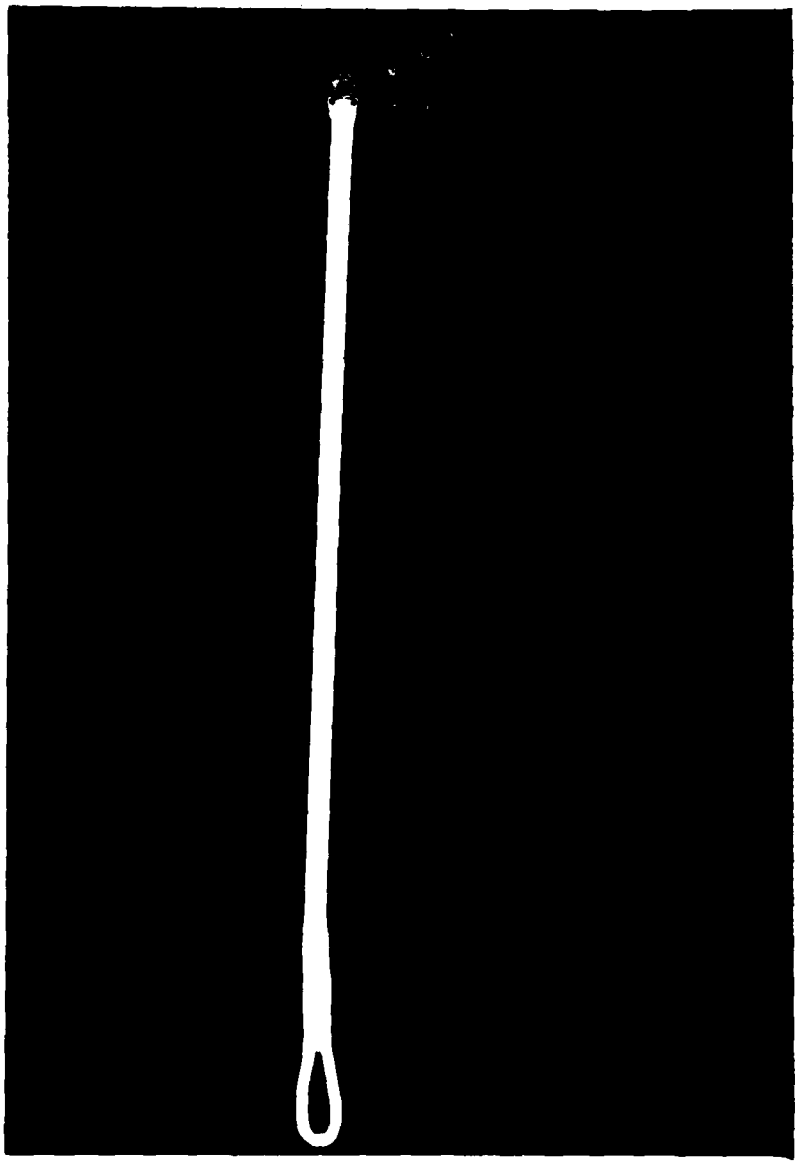

FIGURE 2

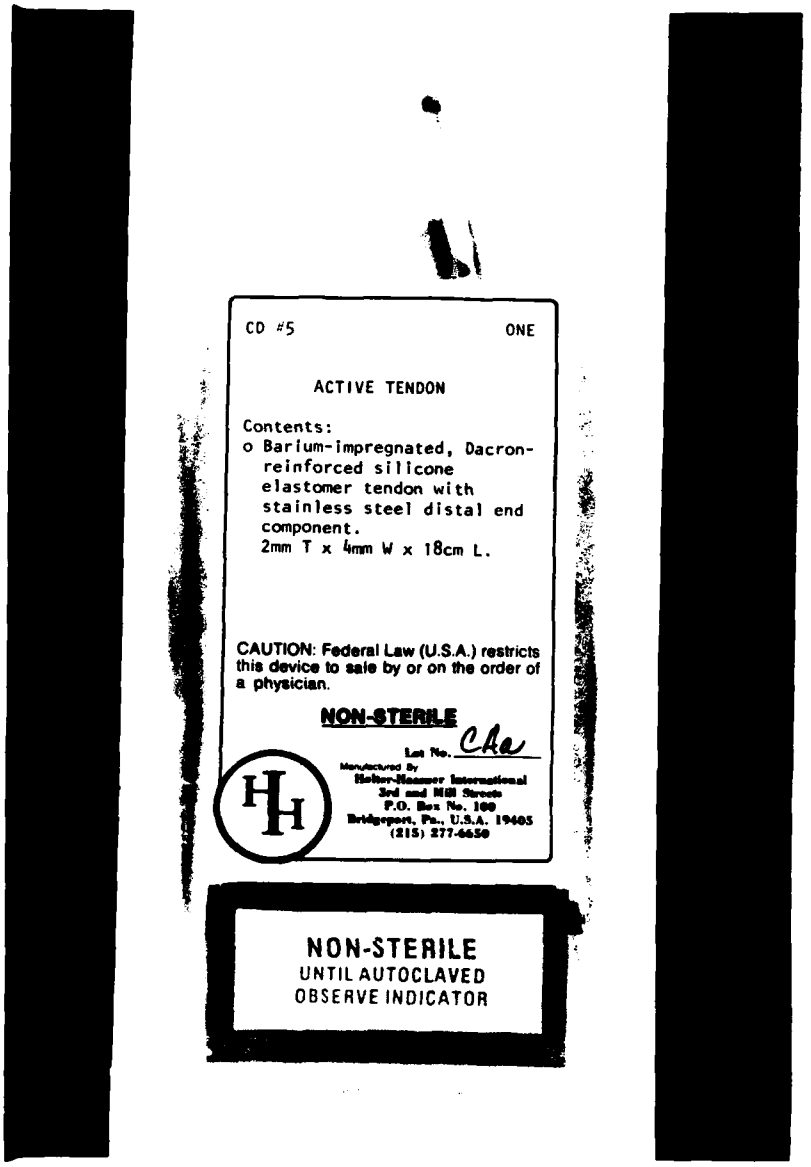
CD #5
ONE
ACTIVE TENDON
Contents:
o Barium-impregnated, Dacron-reinforced silicone elastomer tendon with stainless steel distal end component.
2mm T x 4mm W x 18cm L.
CAUTION: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.
NON-STERILE
Lot No. Cha
Manufactured By
Holter-Hammer International
3rd and Mill Streets
P.O. Box No. 100
Bridgeport, Pa., U.S.A. 19405
(215) 277-6650
NON-STERILE
UNTIL AUTOCLAVED
OBSERVE INDICATOR

FIGURE 2-A

constant measured excursion. A 100% standard angle, a summation of joint angles at full flexion, was determined in the intact pulley systems. The effects of various pulley resections and reconstructions were studies. the anatomical two tendon system and a one tendon system using a passive tendon implant simulating a tendon graft situation, were illustrated and compared. Pulleys were reconstructed first with brass wire to test hypothesis: then by tendon graft through bone to bear out their clinical significance. Resection of all three cruciates as well as A_5 gave a total active motion (T.A.M.) of 98%, thus representing the preferred locations for exploration of the tendon sheath. The major pulleys to be left intact for optimal function are A_1, A_2, A_3, A_4, in their entirety. With serial pulley resections, DIP flexion fell off much more dramatically than that of other joints which often were able to compensate by a mild increase of motion. This buffered the final effect on TAM. This loss of DIP motion reflects reduced tendon gliding due to bowstringing of the flexor tendon. The resultant joint range of motion is inversely proportional to the radius from the center of rotation of the joint to the flexor tendon. Placing pulleys at the bases of the proximal and middle phalanges, just distal to the joints, minimized the radius and maximizes the range of motion by decreasing tendon bowing. Interference with the volar plate and collateral ligaments precludes placement of pulley close to the proximal aspect of joints. Bowing of the tendon results in many problems and potential disasters. (1) a decreased range of joint motion, (2) flexion contractures of the joint, (3) tendon adhesions, (4) decreased flexion power, (5) increased risk of pulley rupture. A series of tendon graft pulley reconstructions showed significant improvement in TAM and decreased bowing and its associated hazards, with the addition of each consecutive

pulley in reconstructing a four pulley system. Locating pulleys at the bases of the proximal and middle phalanges significantly improved results, as did the addition of an A_1 pulley around the metacarpal neck. The five pulley system with further pulleys in the distal A_2 and A_4 positions is proposed as optimal.

B. Visco Elastic Studies

TEXTILE LABORATORY STATISTICS ON SPECIALLY TEXTURED DOUBLE LOOP TENDON SHAFTS

These samples have been heat set and pressed (flattened). (Fiqure 1) The braided tendon shafts have been tested on a tensile at various rates of extension. The results based on 10 trials for each rate of extension are as follows:

Extension Rate (mm/min)	Breaking Load(kg)	Breaking Elongation (%
5	91 + 2.2	19
50	92 + 4.2	19.6
500	93 + 2.3	20

Please note that rupture always occurred at the center of the braid. This means the loops were placed securely in the shaft.

An additional study was also done to evaluate the effect of the length of insertion. The results of that study comparing the properties of human tendon with the artificial tendons is summarized in the attached table. (Table 1) We feel that the artificial tendon can meet human stress-strain requirements.

TABLE 1
STRESS STRAIN PROPERTIES
OF
HUMAN AND ARTIFICIAL TENDONS

Properties	Human Tendon Ambient Physiological Conditions		Artificial Tendon Insertion Length		
			2.5"	4"	4.5"
Breaking Stress (Kg/mm^2)	3.96	5.49	60.93	61.97	62.72
Breaking Elongation (%)	18.10	30.30	30.57	25.88	23.87
Initial Modulus (Kg/mm^2)	27.50	26.30	179.93	161.72	135.67

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Summary: There was consistent orderly development of new sheaths in response to a static implant.

2. SHEATH FORMATION IN RESPONSE TO LIMITED ACTIVE GLIDING IMPLANTS (Animals), James M. Hunter, David Subin, Frederick Minkow, and John Konikoff, Journal of Bio-Medical Material Research Symposium, No. 5, part 1, pages 163-173, 1974.

Summary: A gliding implant can convert a non-specific bed of connective tissue or scar into a specific lining envelope comparable to the tendon sheath. This system has been shown to be capable of lubricating and supporting a gliding artificial implant while augmenting normal tendon function. Degrees of active and passive gliding can take place for indefinite periods providing the mechanical dynamic capabilities of the new system are understood and controlled in which the matured sheath will show a predictable physiological response to unfavorable stimuli.

3. THE ACTIVE GLIDING TENDON PROSTHESIS: PROGRESS, James M. Hunter and Scott H. Jaeger, American Academy of Orthopedic Surgery: Symposium on Tendon Surgery in the Hand, pages 275-282, 1975.

Summary: The progress of the production of an active gliding tendon prosthesis with discussion of the tendon prosthesis shaft, the junctural interfaces and the use of bone ingrowth as an attachment to bone.

4. NEW CORE MATERIAL FOR ACTIVE TENDON PROSTHESIS, Robert H. Huxster, Scott H. Jaeger, William Rostoker, and James M. Hunter. Orthopedic Transactions, 1976.

Summaryf: Discusses Kevlar, a new biomaterial. Found that Kevlar is well suited for use in active artificial tendons as its physical properties are similar to or better than collagen. It is bio-compatible, resistant to bio-degradation and stands up well to flexion fatique. The possibilities of Kevlar in the repair of various other collagenous substances cannot be ignored.

- Continued -

5. SOFT TISSUE ATTACHMENTS OF ACTIVE TENDON PROSTHESES USING A BONE-MODULUS BUFFER GRADED INTERFACE. Scott H. Jaeger, Robert Huxster, and James M. Hunter. Orthopedic Transactions, 1976.

   Summary: Results indicate that the use of a bone graft in conjunction with sintered titanium can produce a graded interface with muscle. This graded interface is strong and durable even soon after implantation, and it offers a technique for attaching the proximal aspect of an active tendon prosthesis to flexor muscles. In addition, the technique may have use in other areas where soft tissue attachments to prosthesis are required.

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